Three Quality Journeys – Capability Maturity Model® Integration, Baldrige Performance Excellence Program, and ISO 9000 Series

Software Engineering Institute
Carnegie Mellon University
Pittsburgh, PA 15213

Charlene C. Gross
Jon L. Gross
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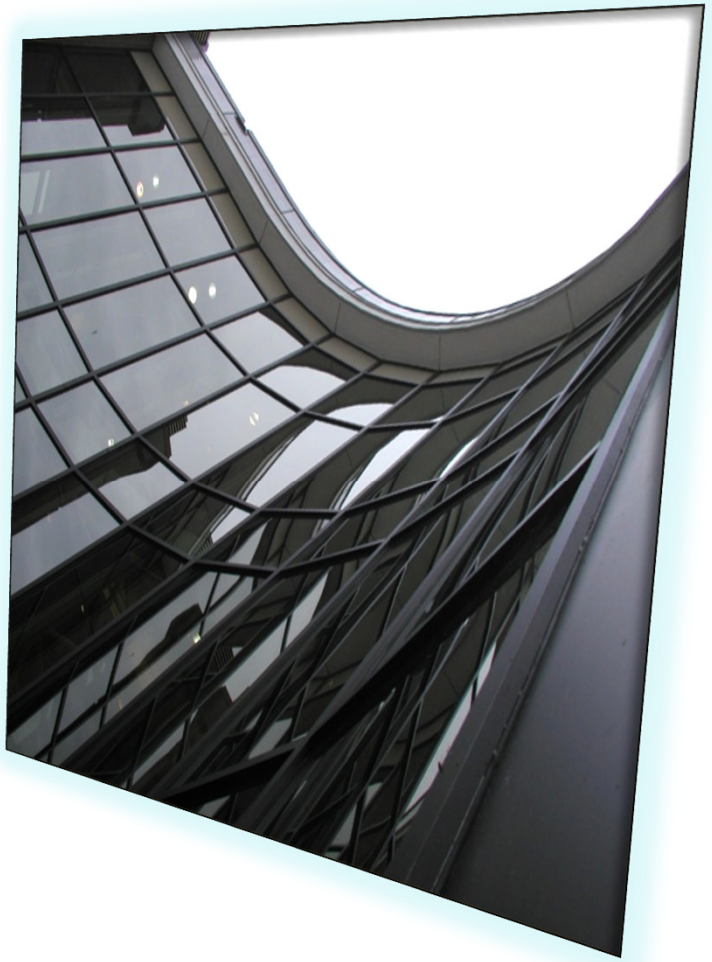
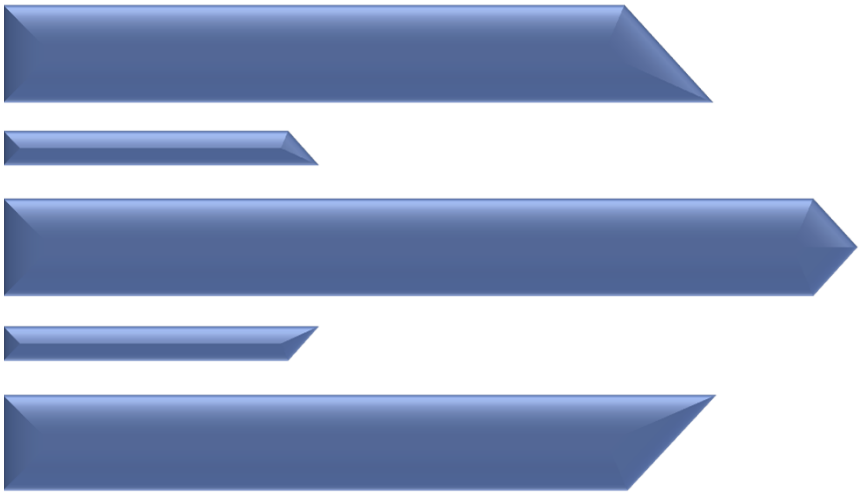
Objectives

- Provide a high-level overview of the origins, foundations, goals, and scope of each approach.
- Compare and contrast support for quality and performance improvement
- Present real-world examples of a multi-model environment that utilized at least two of the approaches
- Identifies improvement “truths” that apply across the three approaches

About the Software Engineering Institute (SEI)

- Federally Financed Research and Development Center (FFRDC)
- Sponsored by the Office of the Undersecretary of Defense (OUSD) for Acquisition, Technology, and Logistics (AT&L)
- Created in 1984 under contract awarded to Carnegie Mellon University
- Offices in Arlington, VA; Pittsburgh, PA; and Frankfurt, Germany
- **Steward** of the Capability Maturity Model Integration





High Level Overview

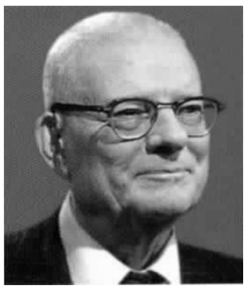
Shared History

In the 1930s, Walter Shewhart began work in improvement with his principles of statistical quality control.

Walter Shewhart

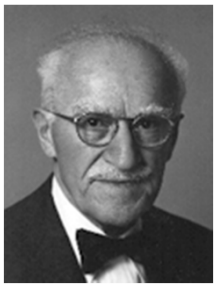
The theories of process management are a synthesis of the concepts and principles refined by:

- W. Edwards Deming
- Phillip Crosby
- Joseph Juran



W. Edwards Deming

Phillip Crosby



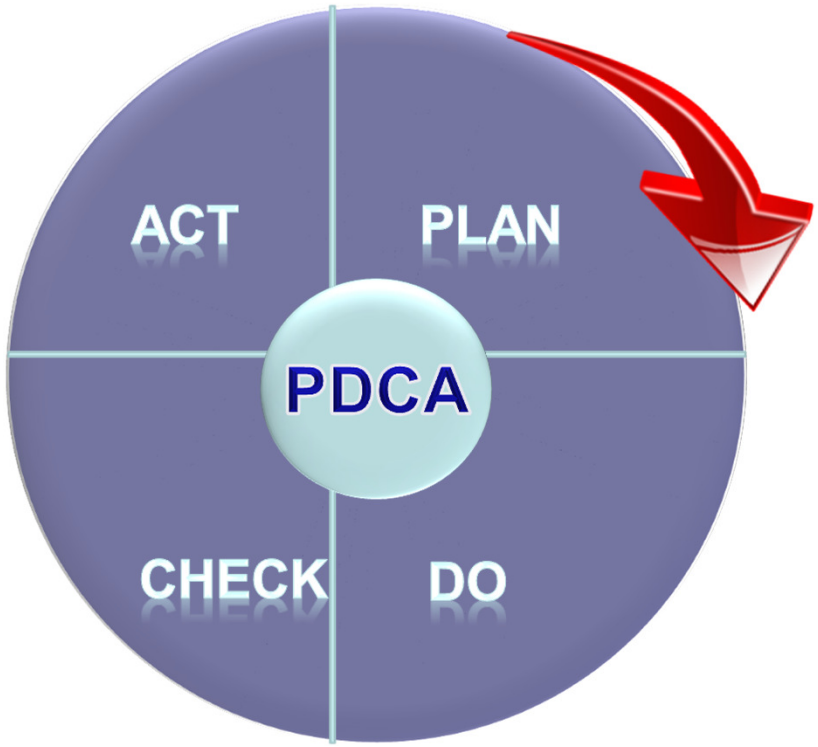
Joseph Juran

Over the past decades, these theories have informed various frameworks for improvement of quality and performance.

Source: CMMI® for Development, Version 1.3, November 2010
Source: The Capability Maturity Model: Guidelines for Improving the Software Process. 1995

Shared Foundation – Plan-Do-Check-Act

- Originated in the 1920's with Shewhart
- Popularized by Deming, who later described it as Plan-Do-**Study**-Act
- Now considered a classical approach to continuous quality improvement
- Shared by CMMI, Baldrige, and ISO as a basic foundational principle



http://www.iso.org/iso/iso_catalogue/management_standards/management_system_basics

Goals of the Capability Maturity Model Integration (CMMI)

CMMI models help organizations improve their processes and focus on activities for developing quality products and services to meet the needs of customers and end users.

Scope of CMMI

CMMI has been described as a "de facto" standard with 77 countries reporting appraisals. An estimated 1.8 million people work in organizations that have had at least one appraisal since April 2002.

The CMMI constellations address improvement of processes for development of products, acquisition, and services for industry and government.

Origins of CMMI®

Watts Humphrey, Ron Radice, and others extended quality principles to software in their work at IBM.

Humphrey's book, **Managing the Software Process**, provides basic principles and concepts on which many of the Capability Maturity Models® (CMMs®) are based.)

Beginning in 1986, the SEI and MITRE Corporation, under the direction of Watts S. Humphrey, began developing a process maturity framework to help organizations improve their products.

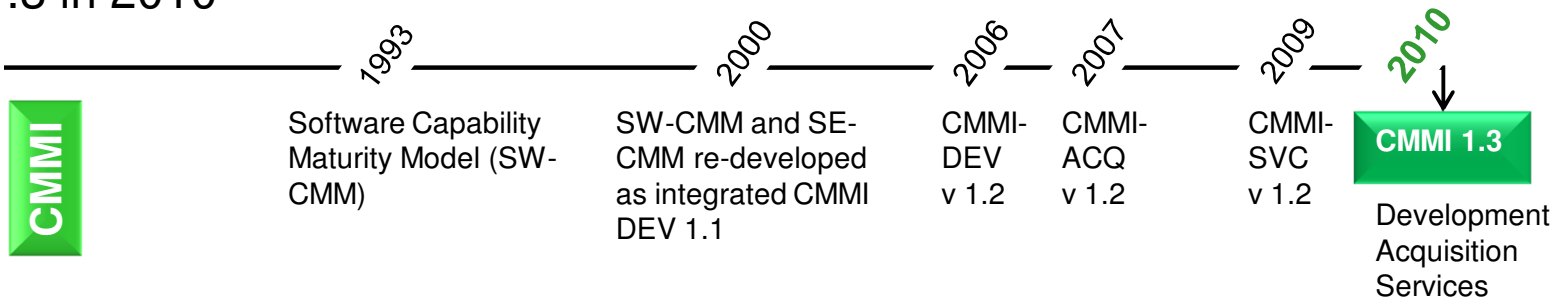
Watts Humphrey

- Response to government request for method to assess capability of software contractors.
- Software process assessment method and software capability evaluation developed, with a maturity questionnaire to appraise software process maturity.

Source: CMMI® for Development, Version 1.3, November 2010
Source: The Capability Maturity Model: Guidelines for Improving the Software Process. 1995

Progression of the Capability Maturity Model Integration (CMMI)

- Initial release of the CMM reviewed and used by software community during 1991 and 1992. CMM V1.1 was released February 1993.
- Capability Maturity Model (CMMI) Integration released in 2000; integrated Capability Maturity Model for Software, v2.0 draft C (SW-CMM), Systems Engineering Capability Model (SECM), and Integrated Product Development Capability Maturity Model (IPPD-CMM) v0.98.
- CMMI expanded to provide multiple constellations - CMMI-DEV 1.2 (2006), CMMI for Acquisition (2007), and CMMI for Services (2009).
- Coordinated cross-constellation revision and upgrade released as Version 1.3 in 2010



Source: CMMI® for Development, Version 1.3, November 2010

Goals of Baldrige

The Baldrige Program's mission is to improve the competitiveness and performance of U.S. organizations. It promotes quality awareness, recognizes achievements of U.S. companies, and publicizes successful strategies.

Scope of Baldrige

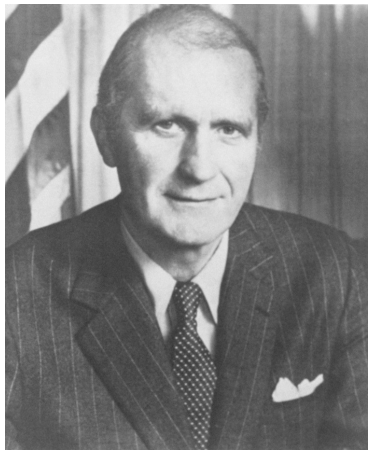
The Award is presented annually to up to 18 United States companies by the President of the United States. There have been 95 award recipients since 1988 across six organizational categories:

- manufacturing companies,
- service companies,
- small businesses,
- education organizations,
- health care organizations, and
- nonprofit organizations.

Source: 2011–2012 Criteria for Performance Excellence, Malcolm Baldrige National Quality Award

Origins of Baldrige Award

Malcolm Baldrige was a proponent of quality management as a key to United States prosperity and long-term strength. He drafted one of the early versions of a national quality act.



Malcolm Baldrige

At a White House Conference in 1983, Baldrige, along with the other delegates, strongly believed that the issue of quality should be addressed (Bogan and Hart). They decided that they wanted something similar to Japan's Deming Prize, but more unique to the United States.

Presented in 1987 as The National Quality Improvement Act, it was renamed the Malcolm Baldrige National Quality Award Act after his untimely death, and passed by Congress.

Congress voted to withdraw funding for the Baldrige program in the 2012 federal budget.

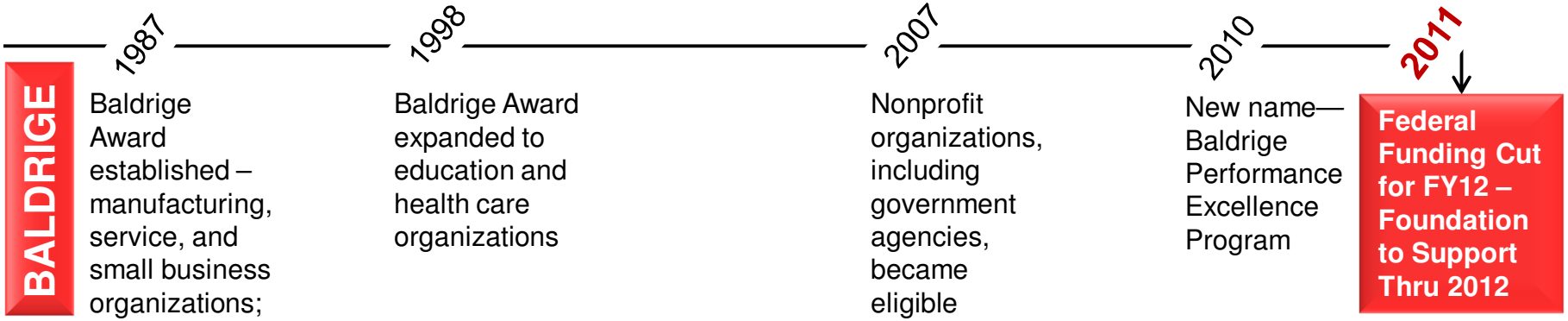
Source: "Ten Years of Business Excellence for America," NIST NOVEMBER 1998
Source: Bogan, Christopher E., Hart, Christopher W. L. (1992). The Baldrige. New York: McGraw-Hill, Inc.

Progression of the Baldrige Criteria

Dr. Curt Reimann, the first director of the Malcolm Baldrige National Quality Program, and his staff at the National Institute of Standards and Technology (NIST) advanced proposals for what is now the Baldrige Award in 1987.

Criteria have evolved from a specific focus on manufacturing quality to a comprehensive strategic focus on overall organizational performance, competitiveness, and sustainability.

It is considered America's highest honor for business performance excellence.



Source: Wikipedia, http://en.wikipedia.org/wiki/Malcolm_Baldrige_National_Quality_Award

Goals of the ISO 9000 Series

The ISO 9000 family addresses fulfillment of the customer's quality requirements and applicable regulatory requirements while aiming to enhance customer satisfaction and achieve continual improvement.

Scope of ISO 9000

ISO 9000 Series represents an international consensus on good quality management practices. ISO 9001:2008 has been implemented by over a million organizations in 176 countries.

http://www.iso.org/iso/iso_cafe_management_systems.htm

Origins of ISO 9000 Series

The organization's name, which is officially ISO, comes from the Greek word "isos" meaning "equal" (if two objects meet the same standard, they should be equal)

- Organized as an international standards body in 1946
- Initially addressed standards related to basic mechanics, such as screw threads, ball and roller bearings, and gears
- Membership now made up of 163 national standards institutes (31 Dec 2010)

Willie Kuert, last surviving delegate to 1946 conference

- ISO has developed over 18,500 International Standards, each representing a national consensus position based on stakeholder views of each country

As part of the evolution in the certification of quality, ISO developed the ISO 9000 series:

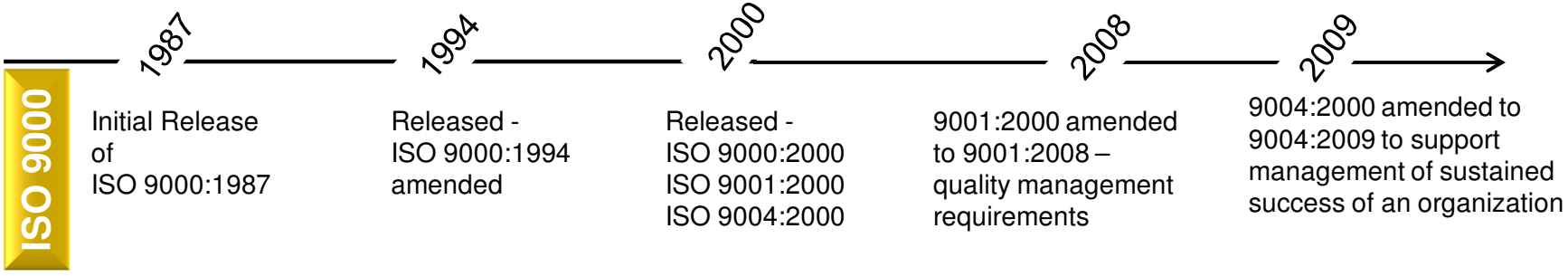
- Expanded from certification of quality to certification of the management of quality
- Responded to companies' desire to organize their own approach to the problem of quality

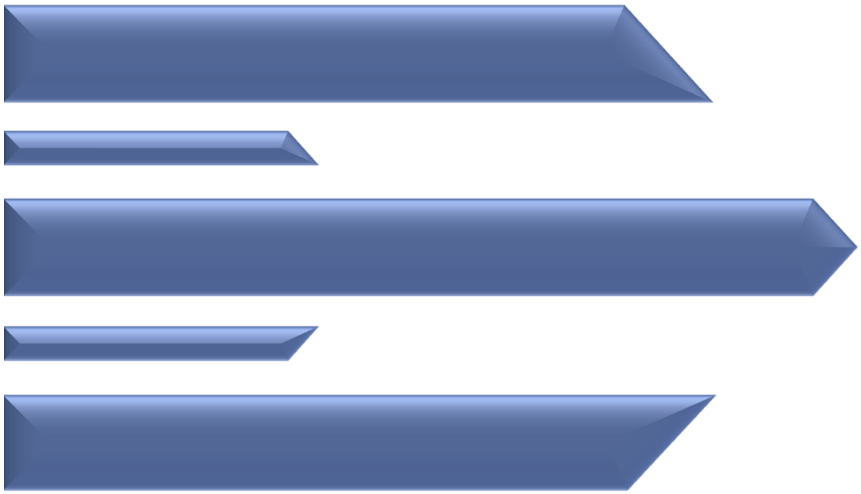
Source: Raymond Frontard, Former Director-General of AFNOR, in "Standards Related Activities"

Progression of the ISO 9000 Series

ISO 9000:1987 series consisted of ISO 9000, offering fundamentals and vocabulary; and **three 9001 models** emphasizing conformance to procedures - ISO 9001 (new products), ISO 9002 (installation and services), and ISO 9003 (final inspection and test). **ISO 9000:1994** series emphasized quality assurance via **preventive actions. ISO 9000:2000** series **combined** 9001, 9002, and 9003 into **9001:2000** and introduced **ISO 9004:2000.** Revisions and clarifications of **9001 and 9004** occurred in 2008 and 2009, respectively

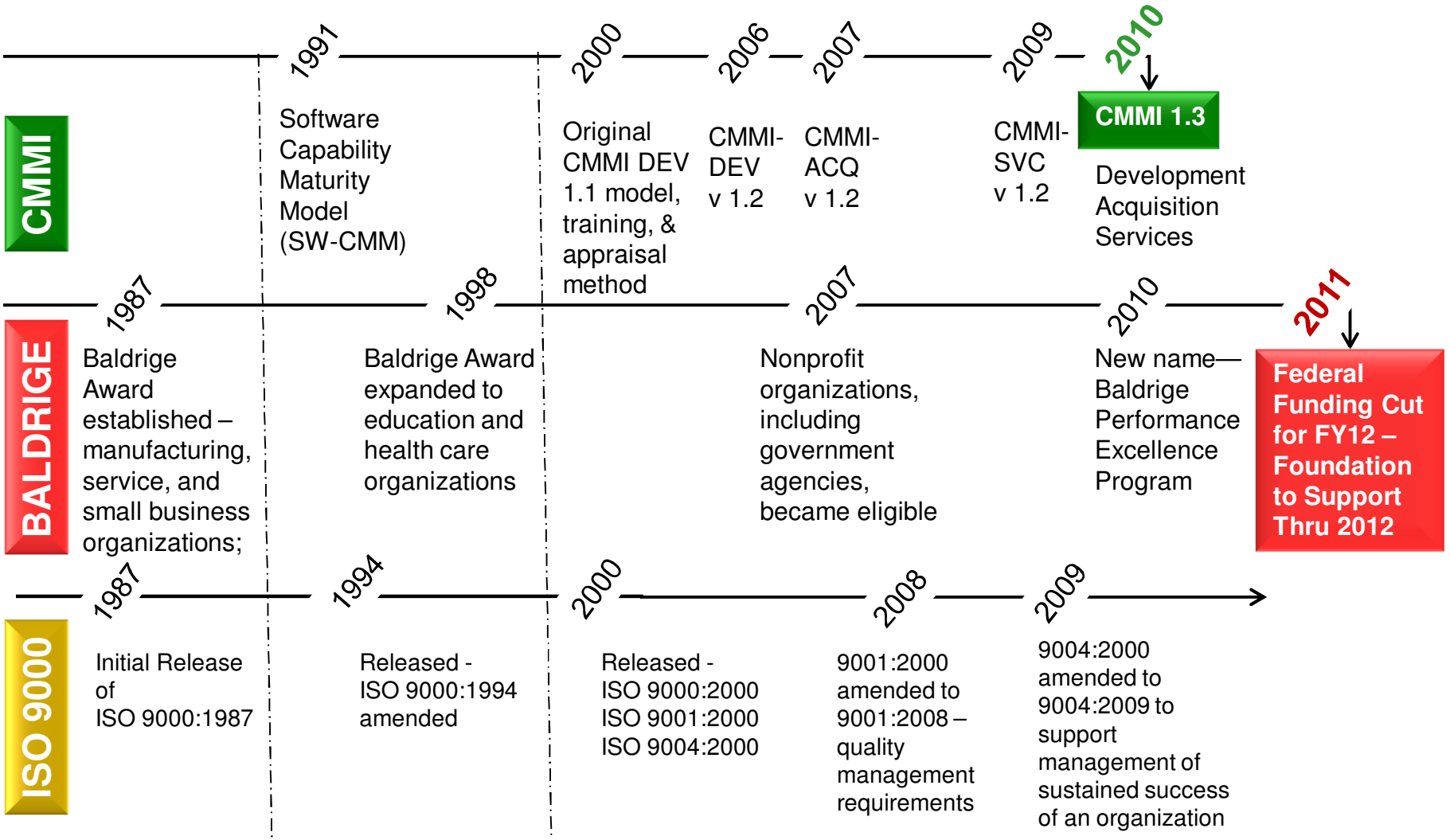
- ISO 9001:2000 - **eight quality management principles**, process performance metrics; explicit expectations of continual process improvement and tracking customer satisfaction; and radical change to emphasis on process management; also demands involvement by upper executives in order to integrate quality into the business.
- ISO 9004:2000 standard provided method for sustaining organizational success





Comparisons – CMMI, Baldrige, and ISO 9000 Series

Comparative Timelines



High Level Comparison – Structure and Focus

Comparison of:	CMMI Model	Baldrige Criteria	ISO 9000 Series
Responsible Organization	Software Engineering Institute/Carnegie Mellon; DOD Federally Funded Research and Development Center	National Institute of Standards and Technology (NIST), US Department of Commerce	Technical Committee 176 of ISO - International Standards Organization
Goal	Improve product quality by improving process quality	Improve competitiveness and performance of US organizations	Improve quality by improving management of quality
Applicability	International	United States	International
Organizational types	Generic for product development, services, and acquisition in any organization	(1) Manufacturing (2) Service (3) Small business (4) Education (5) Health care (6) Nonprofit	Generic for quality management in any organization

High Level Comparison – Structure and Focus

Domain	CMMI Model Framework	Baldrige Criteria Framework	ISO 9000
High level components	Models, training, appraisal methodology	Criteria, examination process	Definitions (9000), quality management requirements (9001:2008), improvement sustainment (9004:2009)
Structural Elements	Structured by process areas and overarching generic practices	Structured by Criteria categories	Structured by quality management sections
Achievement Structure	Maturity level (ML 2 – 5) and/or capability level (CL 1 – 3) rating	Malcolm Baldrige National Quality Award	9001:2008 certification

CMMI Focus

Generic Goals and Practices

Generic Goal 1 - Achieve Specific Goals

- GP 1 – Perform specific practices

Generic Goal 2 – Institutionalize Managed Process

- GP 2.1 – Organization Policy
- GP 2.2 – Process Plan
- GP 2.3 – Resources
- GP 2.4 – Responsibility
- GP 2.5 – Training
- GP 2.6 – Product Control
- GP 2.7 – Stakeholder Involvement
- GP 2.8 – Process Monitoring and Control
- GP 2.9 – Objective Evaluation
- GP 2.10 – Management Review of Status

Generic Goal 3 - Institutionalize a Defined Process

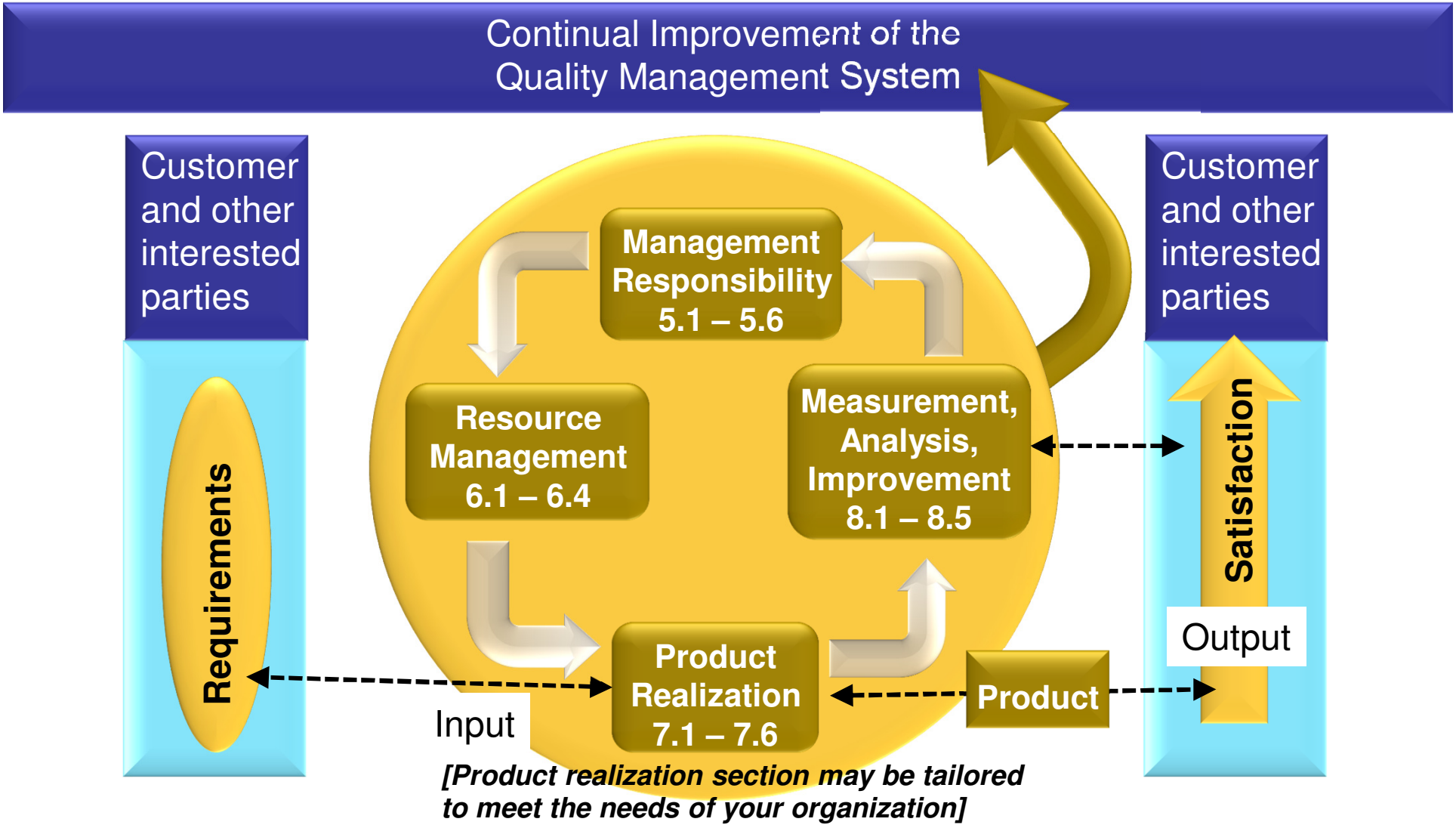
- GP 3.1 – Establish a Defined Process
- GP 3.2 – Collect Process Related Experiences

Core Process Areas	Maturity Level
• Configuration Management	2
• Project Monitoring and Control	2
• Project Planning	2
• Process and Product Quality Assurance	2
• Requirements Management	2
• Measurement and Analysis	2
• Decision Analysis and Resolution	3
• Integrated Project Management	3
• Organizational Process Definition	3
• Organizational Process Focus	3
• Organizational Training	3
• Risk Management	3
• Organization Process Performance	4
• Quantitative Project Management	4
• Causal Analysis and Resolution	5
• Organizational Performance Management	5

Baldrige Focus

Source: 2011–2012 Criteria for Performance Excellence, Malcolm Baldrige National Quality Award

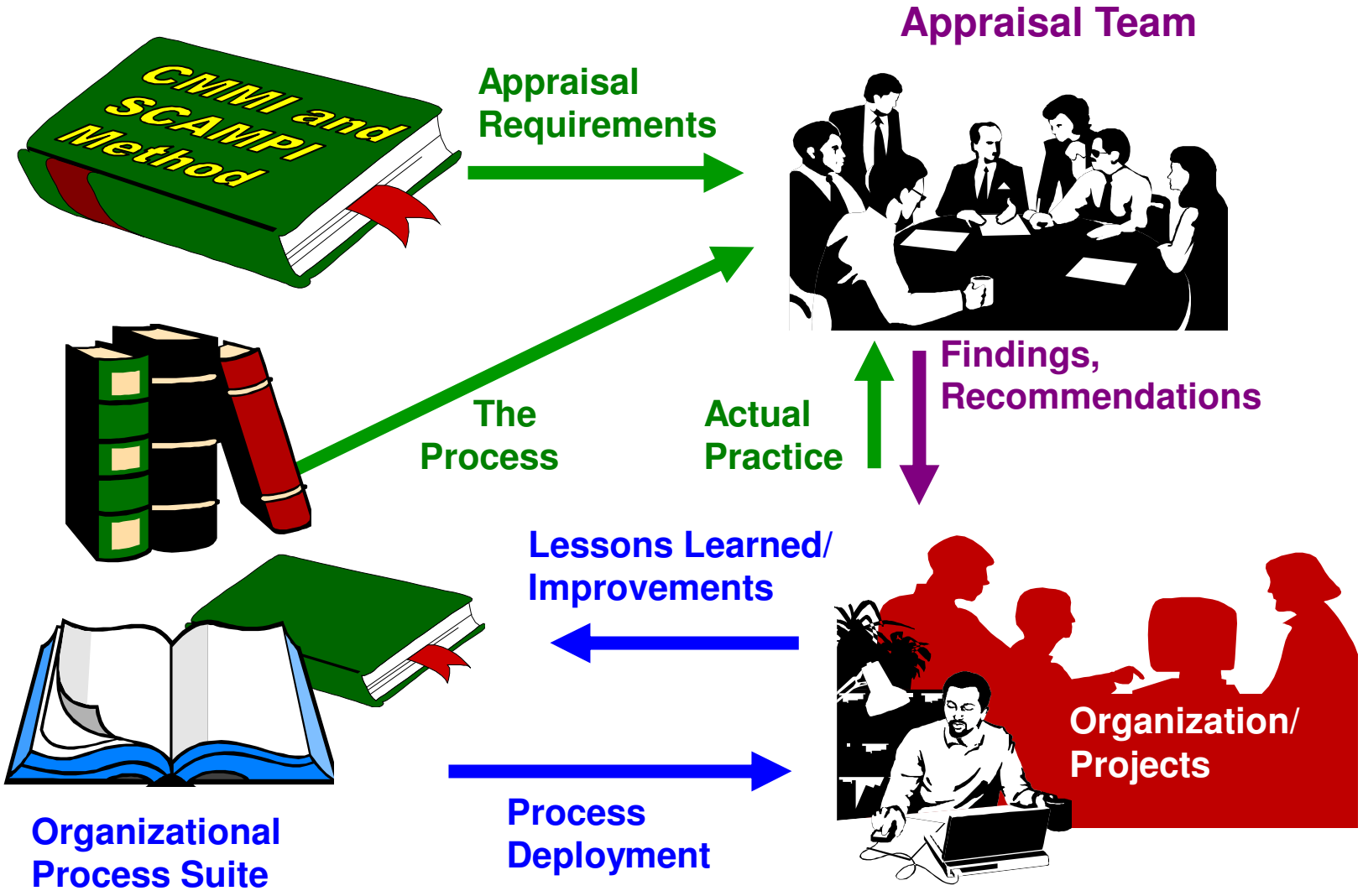
ISO 9001:2008 – Focus



High Level Comparison - Evaluation

Comparison of:	CMMI Model	Baldrige Criteria	ISO 9000 Series
Evaluation Method	**Appraisal** is based on model goals and practices	**Examination** is based on what the organization considers important, as described in the organizational profile	**Certification** is based on 2001:2008 compliance
Evaluation framework	Rating by maturity level of organization unit (ML) or by capability level of process area (CL)	Organizational examination to earn award	Organizational certification
Lead for evaluation	Lead Appraiser of Standard CMMI model	Lead of Baldrige examiner team	External Lead auditor from authorized certification body
Frequency of renewal	Every three years	Award recipients ineligible for the award again for five years	Initial audit; interim audits at least every 12 months; major re-certification after 3 years

SCAMPI Appraisal



Baldrige 2012 Examination

Organizational Profile that is completed by applicant sets context for how organization operates AND for the application review. Scoring values for each Baldrige area are shown below:

1 Leadership (120 points)

- 1.1 Senior Leadership (70)
- 1.2 Governance and Societal Responsibilities (50)

2 Strategic Planning (85 points)

- 2.1 Strategy Development (40)
- 2.2 Strategy Implementation (45)

3 Customer Focus (85 points)

- 3.1 Voice of the Customer (45)
- 3.2 Customer Engagement (40)

Baldrige 2012 Examination (cont.)

4 Measurement, Analysis, and Knowledge Management (90 points)

- 4.1 Measurement, Analysis, and Improvement of Organizational Performance (45)
- 4.2 Management of Information, Knowledge, and Information Technology (45)

5 Workforce Focus (85 points)

- 5.1 Workforce Environment (40)
- 5.2 Workforce Engagement (45)

6 Operations Focus (85 points)

- 6.1 Work Systems (45)
- 6.2 Work Processes (40)

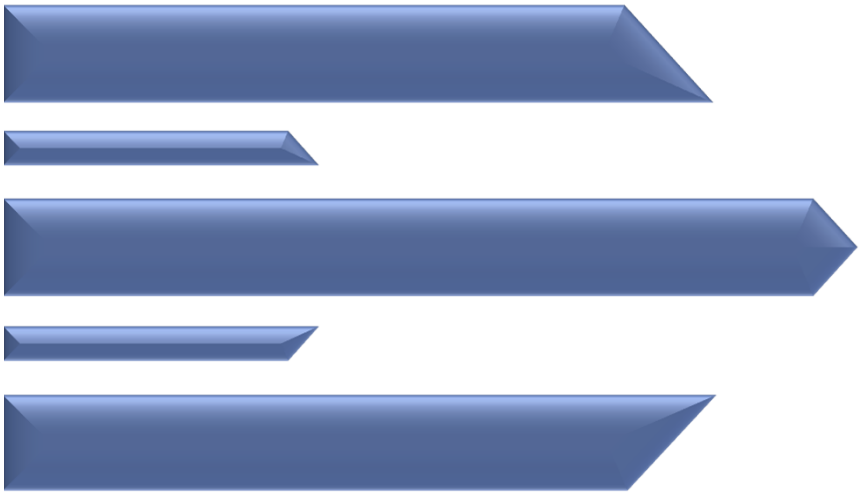
7 Results (450 points)

- 7.1 Product and Process Outcomes (120)
- 7.2 Customer-Focused Outcomes (90)
- 7.3 Workforce-Focused Outcomes (80)
- 7.4 Leadership and Governance Outcomes (80)
- 7.5 Financial and Market Outcomes (80)

ISO 9001:2008 Implementation, Certification, and Ongoing Maintenance

- From the start of the project to the initial certification audit by certification body auditor is about six months
  - Depends on resources, size, and complexity
  - Internal audit is typically scheduled 2 months prior to each external audit to allow corrective actions prior to external audit
  - Instant certification not possible because must have records that demonstrate use of the quality system
- Usually have a surveillance audit by external auditor six months after initial certification
- Thereafter, external audits are conducted at least every 12 months, and sometimes every 6 months - depending on the business
- A major re-certification audit takes place after three years to renew the ISO 9001 certificate

Quality Systems. http://www.qualitysystems.com/support/display/qst/ISO+9001+Timeline+-+Implementation+and+Ongoing+Management



Case Studies

Case Study #1 – CMMI + Baldrige

Utilizing both CMMI and Baldrige Criteria for Performance Excellence approach.

Example Profile:

- US Government Organization providing health care administration and services.
- Improvement history in the IT organization spans approximately the last nine (9) years
- The larger enterprise uses Baldrige Criteria for Health Care Organizations.
- The larger enterprise runs an internal program to review individual hospital applications, using the Baldrige Criteria, and provides recognition, based on internal review of hospital applications.

Case Study #1 – CMMI + Baldrige – Major Change

The Information Technology portion of the enterprise started adoption of CMM. IT had earlier experience with Software CMM.

- CMMI model based improvement and adoption was started. A series of SCAMPI Class B and C appraisals were performed to understand process gaps.
- Workforce improvements included Program Management training and encouragement to complete PMI Certified Program Management.
- Improvement action plans were established and being implemented.
- The IT portion had traditionally been improving, but was separate from the enterprise's internal program applying Baldrige Criteria.

Major IT issues caused dramatic leadership and organizational changes in the IT portion of the enterprise, which caused the early CMMI improvement actions to be pushed to the side.

Case Study #1 – CMMI + Baldrige – Blended Approach

New IT leadership that was more hospital-focused began establishing a new organizational structure.

- Baldrige used to organize documentation of new IT organization. Analysis of performance methods informed corrective actions.

Adoption of CMMI for Acquisition and Services and the People CMM were restarted for guidance in operational work processes.

- Acquisition and Services models provided best approaches to performing acquisition and services development and delivery work.
- People CMM provided best approaches to develop workforce.
- CMMI Measurement and Analysis and Goal Question Indicator Measure (GQIM) supported monitoring product/services environment.

By default, a multimodel environment was established.

Case Study #1 – CMMI + Baldrige – Blended Approach Progress

Multiple completed cycles of answering the Baldrige Criteria

- Continued evolution of documentation to performance.
- Set of measures established to address Baldrige Results Criteria, using CMMI Measurement and Analysis and GQIM approaches.
- Neither application for internal Baldrige Application Review Program submitted nor a formal SCAMPI Appraisal performed

Future direction?

- Use of Baldrige Criteria for overall improvement framework.
- Continued multi-model approach with CMMI adoption and focused improvement in both IT services, acquisition, and development; and IT workforce human capital development
- Major political change or major IT system failure always a risk

Case Study #1 – CMMI + Baldrige – Advantages and Lessons

- Enterprise-wide acceptance and internal improvement award based on Baldrige Criteria creates a climate and culture for improvement.
- Baldrige approach provided IT with a healthcare-focused framework for enterprise improvement
- CMMI informed the Baldrige framework with details on best practices for IT acquisition, development, and delivery of products and services
- CMMI framework traditionally assumes that the business focus drives improvement
- Baldrige focuses critical attention of the "Leadership, Strategic Planning, and Customer Focus" and on Performance Results (measurement).
- Baldrige triads lend a holistic way to organize the improvement infrastructure (working groups).

Case Study #2 – CMMI + ISO

Utilizing both CMMI and ISO 9000:2008 approach.

Example Profile:

- US Government Organization providing services to other Agencies
- Improvement history in the organization spans approximately ten years
- Program started with transition of new leader into organization
- New leader brought experience of improvement

Case Study #2 – CMMI + ISO – Major Change

Enterprise applied CMMI for Development to acquisition processes to support Program Management role overseeing Prime Contractor. Change agent had experience with Software CMM at another Government Agency.

- SCAMPI A completed, followed by a period of improvement.
- Emphasis shifted from CMMI for Development to CMMI for Acquisition, with series of SCAMPI Class B and C appraisals planned to understand process gaps.
- Based on SCAMPI B results, organization began considering CMMI for Services as a future SCAMPI focus
- Management demonstrated fatigue with CMMI implementation and questioned the efficacy of implementing CMMI practices.

Leadership and organizational support considered moving toward Baldrige Criteria, creating a possible multimodel environment.

Case Study #2 – CMMI + ISO – Blended Approach

With shifting interests, ISO 9000:2008 was evaluated as a focused approach to quality management going forward.

- Provided status as an international standard and was independent from previously used methods.
- Indicated that ISO 9000:2008 provided roadmap for creating a quality management system that addressed issues specific to this organization.
- In addition, ISO 9000:2008 exhibited significant synergy with both CMMI and Baldrige with emphasis on management ownership, customer requirements, and measurement
- Draft policy, objectives, and quality management manual were presented to the organization

Case Study #2 – CMMI + ISO – Blended Approach Progress

Adoption of CMMI for Acquisition and Services appear to have gained ground

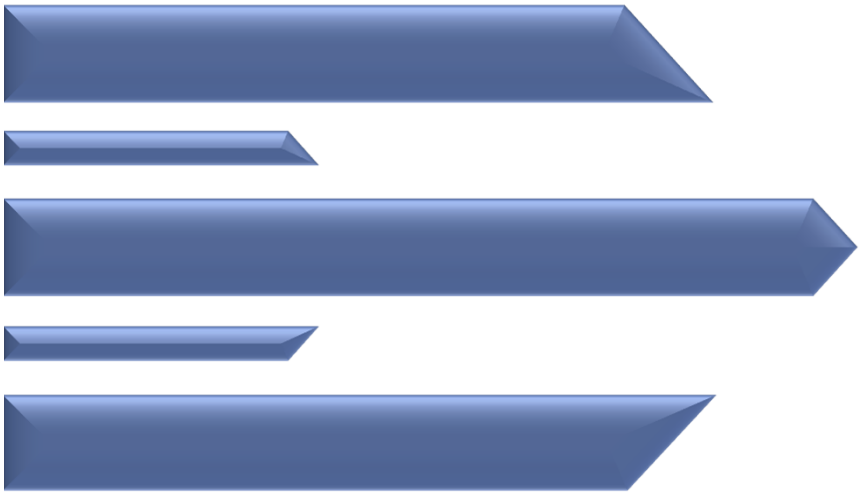
- CMMI for Acquisition and Services models provide best practices to perform acquisition, IT product, and services work

Future direction?

- Organization realignment underway and possible integration with other Government units
- Organization shifted the acquisition strategy and integrated to a higher level organization
- Continued use of CMMI with a shift in focus to the Services model more likely

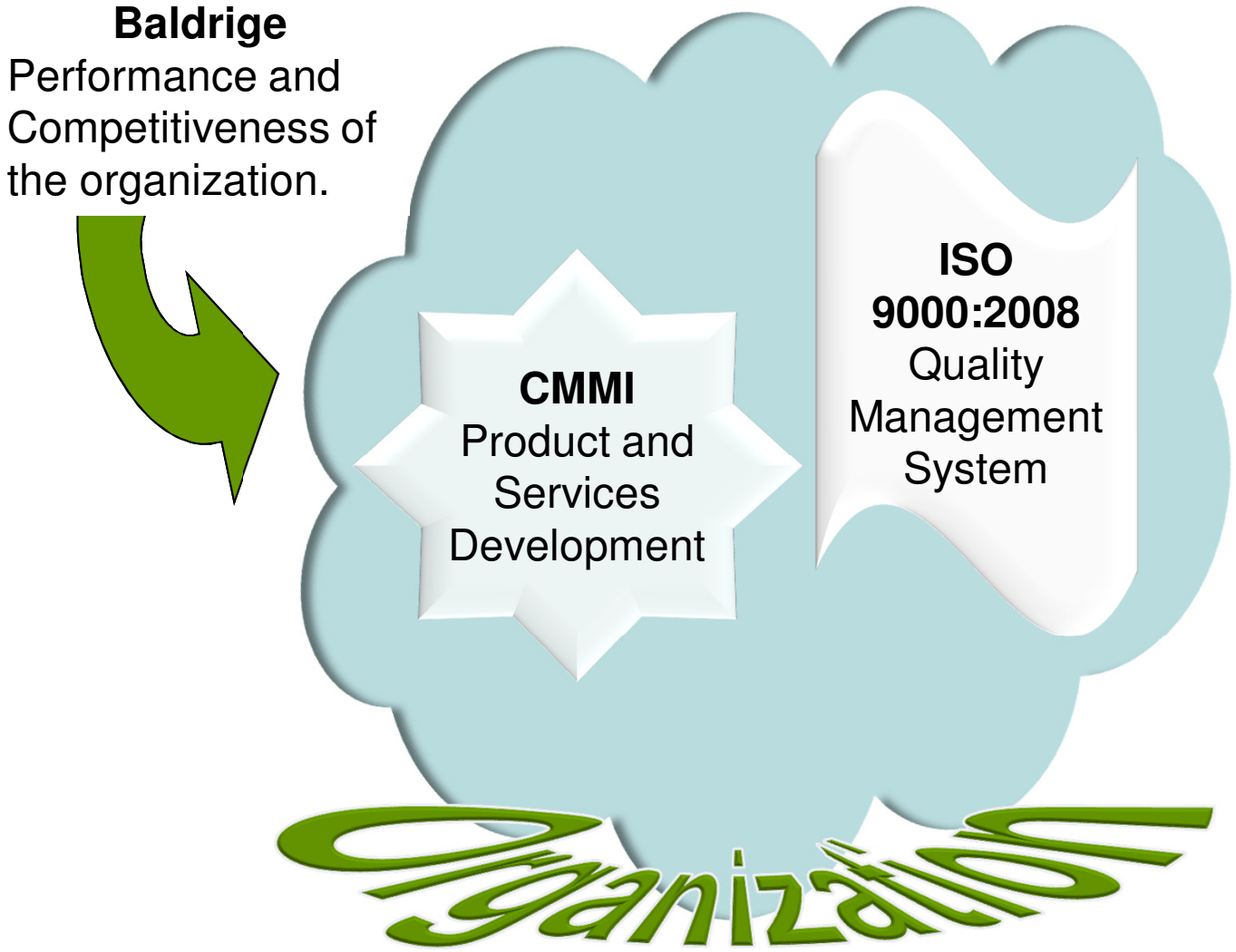
Case Study #2 – CMMI + ISO – Advantages and Lessons

- Both CMMI and ISO 9001:2008 inform implementation of a quality management systems
- Each tool provides a different level of detail on managing quality
- The CMMI framework traditionally depends on and assumes that the enterprise has established and maintained the business focus that drives the improvement of the development and delivery of products and services.
- ISO 9001:2008 clearly states the level of involvement and ownership that must be accepted by senior leadership.

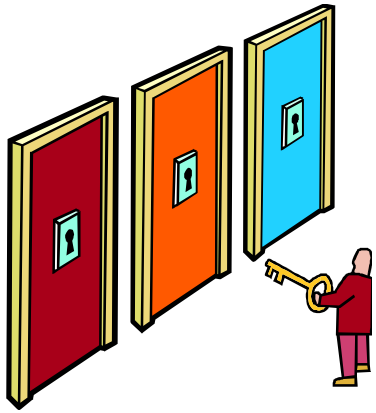


Intersection of Three Journeys

Comparison of Scope



How are These Choices Different?



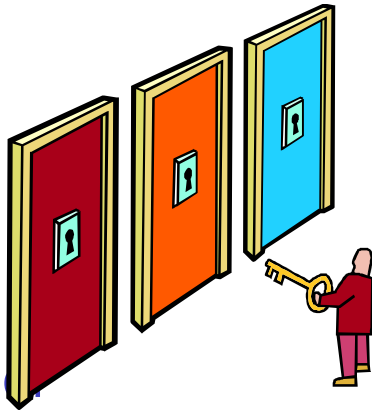
Type of Organization

- Any segment of business or government – CMMI or ISO
- Any type of product or services focusing on quality management – ISO
- Multiple process improvements in technical products or services - CMMI
- US service companies, small businesses, education organizations, health care organizations, and nonprofit organizations – Baldrige

Emphasis

- International Standard – ISO
- International Implementation – CMMI
- Organization Performance Excellence - Baldrige

How are These Choices Different?



Outcome

- Internationally Known Rating of Process Capability Organizational Unit Maturity – CMMI
- ISO Certification of Compliance with International Quality Management Standard – ISO 9001:2008
- Award to US Organization - Malcolm Baldrige National Quality Award

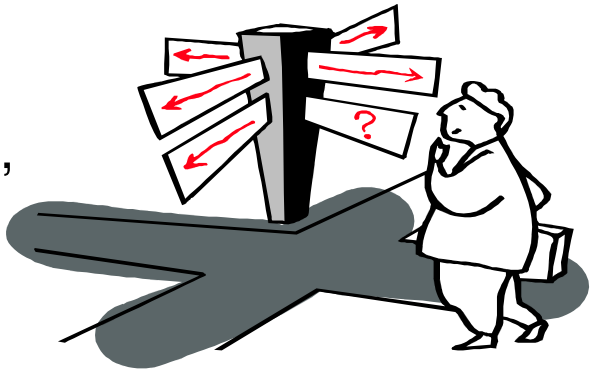
Frequency of Renewal

- Required renewal every three years to retain rating or certification – CMMI, ISO
- Ineligible to apply for award again for five years - Baldrige

Where are the Intersections? Examples

Active involvement by senior management

Emphasis on process management – Documenting, monitoring, and improving processes



Customer Involvement

Quality assurance

Sufficient resources including personnel, training, the facility, and work environment

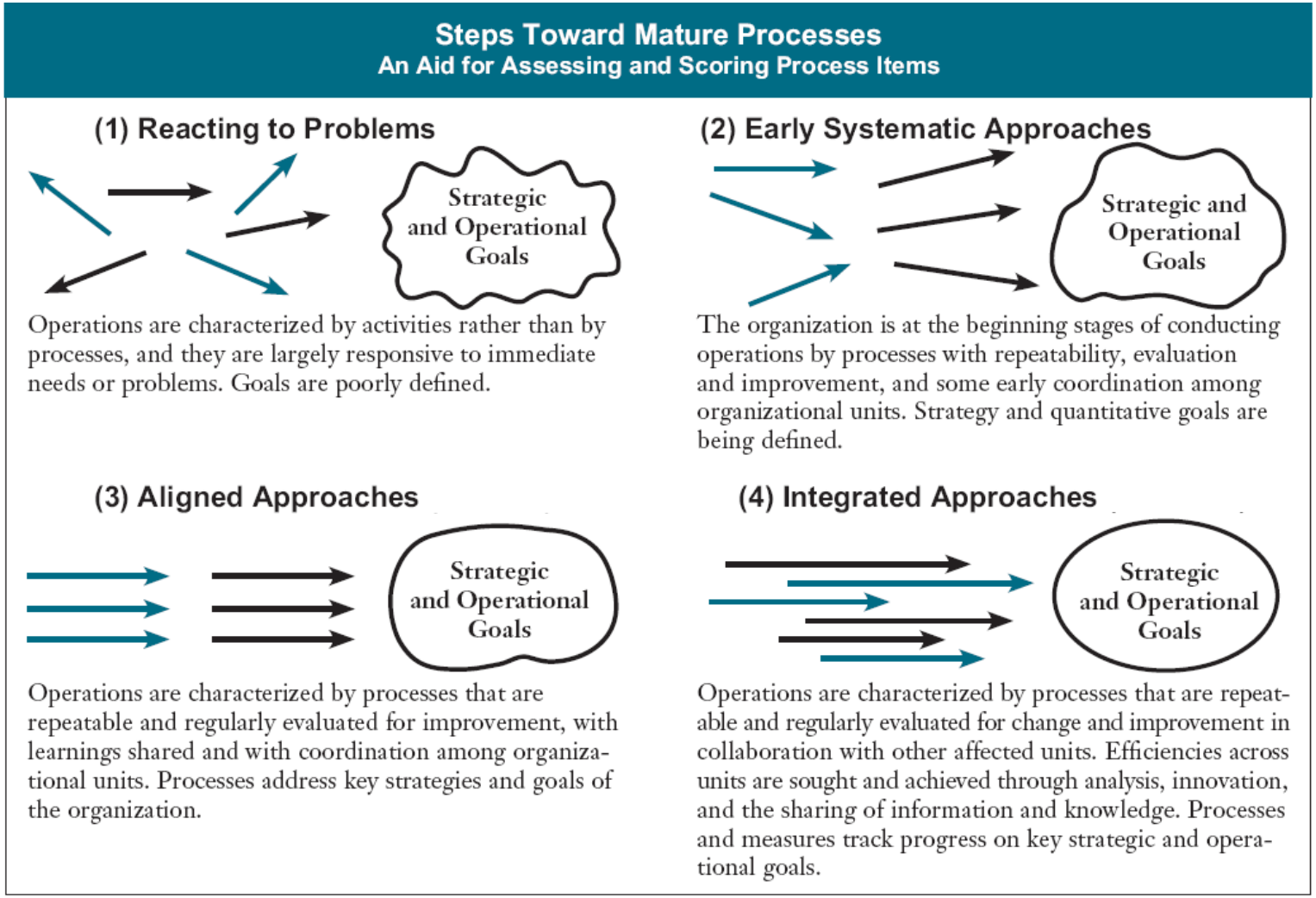
Measures to support decision-making

Records to support claims of use

If you pick any principle of quality or performance, each journey will require that

you address it in some fashion.

Which Approach Does this Represent?



Source: 2011–2012 Criteria for Performance Excellence, Malcolm Baldrige National Quality Award

Bottom Line

Utilizing CMMI, Baldrige Criteria, and/or ISO for quality improvement enriches efforts and benefits each individual approach.

Three Journeys that Support Each Other

"The Quality of the Product is Highly Influenced by the Quality of the Process."

"Excellence is a Journey, Not a Destination"

"Managing the Organization's Processes so that They Consistently Turn Out Product that Satisfies Customers' Expectations"

The #1 Universal Truth

If you are using the standard as a marketing gimmick

(a plaque on the wall; a logo on a website),

or just because a customer requires it,

then the standard will be

a burden, not a benefit."

Anthony, John. http://www.articlecube.com/Article/Iso-9001-Certification/1477710

Summary

Provided a high-level overview of the origins, foundations, goals, and scope of each approach

Compared and contrasted CMMI, Baldrige, and ISO as quality approaches

Presented two real-world examples of evolving multi-model environments that utilized combinations of CMMI, Baldrige, and/or ISO

Described the synergies across all three approaches

Contact Information

Presenter/Point of Contact
Jon L Gross/Charlene C Gross
Senior Members of Technical Staff
Acquisition Support Program
Telephone: +1 412-268-5800
Email: jgross@sei.cmu.edu
Email: cgross@sei.cmu.edu

U.S. Mail
Software Engineering Institute
Customer Relations
4500 Fifth Avenue
Pittsburgh, PA 15213-2612
USA

Web
www.sei.cmu.edu
www.sei.cmu.edu/contact.cfm

Customer Relations
Email: info@sei.cmu.edu
Telephone: +1 412-268-5800
SEI Phone: +1 412-268-5800
SEI Fax: +1 412-268-6257

Acronyms

CMMI – Capability Maturity Model Integration

CMMI-DEV – CMMI for Development

PDCA – Plan-Do-Check-Act

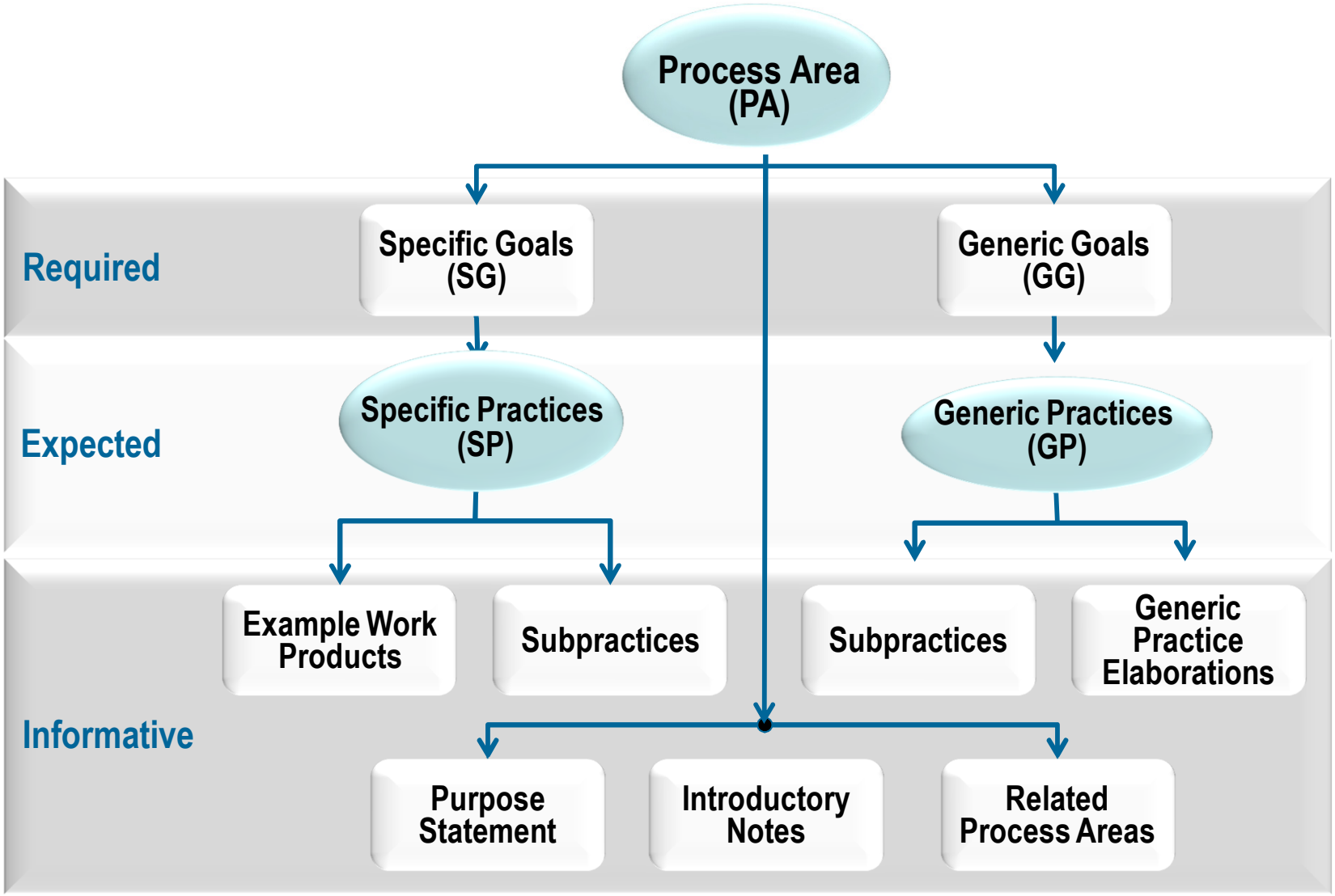
SCAMPI – Standard CMMI Appraisal Method for Process Improvement

SEI – Software Engineering Institute

U.S. – United States

Backup Slides

CMMI Structure



Baldrige Structure

Source: The Baldrige Management Model, http://www.baldrige21.com/Baldrige%20Model.html

ISO 9001:2008 Structure

Section 1: Scope	Talks about the standard and how it applies to organizations
Section 2: Normative Reference	References another document that should be used along with the standard, ISO 9000:2008, Quality Management Systems-Fundamentals and Vocabulary
Section 3: Terms/Definitions	Gives a few new definitions
Section 4: General Requirements	Gives requirements for the overall Quality Management System
Section 5: Management Responsibility	Gives requirements for the overall Quality Management System
Section 6: Resource Management	Gives requirements for resources including personnel, training, the facility and work environment
Section 7: Product Realization	Gives requirements for the production of the product or service, including things like planning, customer related processes, design, purchasing and process control
Section 8: Measurement, Analysis and Improvement	Gives requirements on monitoring processes and improving those processes

CMMI Appraisal Method

Requirements	Class A	Class B	Class C
Types of Objective Evidence Gathered	Documents and interviews	Documents and interviews	Documents or interviews
Ratings Generated	Goal ratings required	Not allowed	Not allowed
Organizational Unit Coverage	Required	Not required	Not required
Minimum Team Size	4	2	1
Appraisal Team Leader Requirements	Lead Appraiser	Person trained and experienced	Person trained and experienced

Source: Appraisal Requirements for CMMI, Version 1.2 (ARC)

Baldrige Application Review

Fixed annual application review schedule (Spring through Fall). The identity of all applicant organizations remains confidential, unless they receive the award.

Application Process

- Two-step process:
  - Submit an eligibility certification package.
  - Submit an award application package - 5 pages of profile information and 50 pages covering 7 criteria categories.

Application Review

- Independent and Consensus Review conducted by a team from the Board of Examiners.
- Site Visit Review for higher-scoring organizations.
- Final reviews and award recommendations by Panel of Judges.

Baldrige Application Review (cont.)

Application Feedback

- Examiner review team provides 2 scores
- How well institutionalized for a category
- How effective measurement program for a category
- Written feedback findings for the applicant to consider for improvement

Award Recipients

- Award recipients may publicize and advertise their awards
- Recipients are expected to share information about their successful performance strategies with other U.S. organizations

Required ISO 9001:2008 Documentation

1. **Document Control** (per ISO 9001 clause 4.2.3) - Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed
2. **Record Control** (per ISO 9001 clause 4.2.4) - Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed.
3. **Internal Audit** (per ISO 9001 clause 8.2.2) - The organization shall conduct internal audits at planned intervals to determine whether the quality management system:
   - conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
   - is effectively implemented and maintained.

Required ISO 9001:2008 Documentation (cont.)

4. **Control of Non-Conformities** (per ISO 9001 clause 8.3) - The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

5. **Corrective Action** (per ISO 9001 clause 8.5.2) - The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements

6. **Preventive Action** (per ISO 9001 clause 8.5.3) - The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements.

ISO 9001 Training. Understanding ISO 9001:2008. Ask Art Solutions. 2006-2010